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EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/03/2003

*Handwritten signature*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/752,533

Applicant(s)

COUTTS ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-63 is/are pending in the application.
- 4a) Of the above claim(s) 32,36,38,44,45 and 51-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-31,33-35,37,39-43,46-50 and 54-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Pursuant to the directives of paper No. 20 (filed 4/25/03), claims 22-26, 28, 36, 41, 42 have been amended, and claims 46-63 added. Claims 22-45 are pending.

Claims 32, 44, 45 remain withdrawn from consideration, as indicated previously. In addition, claims 36, 38, 51-53 are withdrawn from consideration, since they do not encompass the elected specie (compound 3-II, figure 6A).

Claims 22-31 33-35, 37, 39-43, 46-50, 54-63 are examined in this Office action.

Applicants' arguments filed 4/25/03 have been considered and found persuasive in part.

The abbreviation "**VPM**" is used hereinbelow to denote a "valency platform molecule".

The abbreviation "**BAM**" is used hereinbelow to denote a "biologically active molecule".

\*

Claims 22 and 26-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. USP 5276013. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 22 and 26-31 are drawn to (or at least encompass) conjugates of VPM's and polynucleotides. Claim 1 of U.S.P. 5,276,013 is drawn to the same. Thus, there is overlap of the claimed genera.

\*

Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. USP 6,060,056. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 22 is drawn to a (composition comprising a ) conjugate of a VPM and a BAM. Claim 1 of U.S.P. 6060056 is drawn to a conjugate of a VPM and a BAM, wherein the BAM must be an analog molecule of an immunogen. Although the scope of the compounds encompassed by BAM is more limited in the '056 patent than is the case here, there is still overlap between the respective genera. Instant claim 22 does recite a composition, rather than a compound, but compositions are also disclosed in the the '056 patent.

\*

Claim 22 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. USP 5552391. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 22 is drawn to a (composition comprising a ) conjugate of a VPM and a BAM. Claim 9 is drawn to a composition comprising a compound of claim 1 (of the patent); claim 1, in turn, is drawn to a conjugate of a VPM and a BAM.

\*

Claim 22 is rejected under the judicially created doctrine of obviousness-type double

patenting as being unpatentable over claim 9 of U.S. Patent No. USP 5276013. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 22 is drawn to a (composition comprising a ) conjugate of a VPM and a BAM. Claim 1 of USP '013 is drawn to a conjugate of a VPM and a BAM, wherein the BAM must be a polynucleotide duplex. Both the VPM cited in the patent and the BAM are encompassed by the VPM and BAM of instant claim 22.

\*

Claim 22 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Serial No. 08/769041. Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

Claim 22 of 08/769041 is drawn to a conjugate of a valency platform molecule (VPM), and a BAM. The claim in the copending application recites a specific genus of VPM's unlike the the instant claims, which recite any VPM. Although the scope of instant claim 22 is substantially broader than that of claim 22 of 08/769041, there is nevertheless overlap of the claimed genera.

\*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-31 33-35, 37, 39-43, 46-50, 54-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 requires that the conjugate meet both of the following conditions:

- (a) the valency of the VPM is predetermined by the number of branching groups, and
- (b) the number of branching groups predetermines the location of attachment sites for BAM's

It may be the case that descriptive support exists for the first of these (page 19, line 14+). However, this ground of rejection focuses on the second of these limitations. It does not appear that there is descriptive support for the location of attachment sites being predetermined by the number of branching groups. One could just as easily argue that it is the number of "attachment sites" that determines the number of branching groups (rather than the other way around). Or perhaps that the two can vary independently of one another. In any case, applicants are requested to point out the

relevant page and line number where descriptive support may be found.

※

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-24, 26, 29, 30, 58-62 are rejected under 35 U.S.C. §102(e) as being anticipated by Sheridan (USP 5,747,244).

Sheridan discloses compositions which contain a peptide to which is covalently bonded (via a linker) oligonucleotides. The peptide bears amino groups (or other nucleophilic groups) to permit covalent bond formation to occur. Preferred peptides contain lysines. Lysine itself is "branched".

Thus, the claims are anticipated.

※

Claims 22, 26, 27, 29, 30, 58-61 are rejected under 35 U.S.C. §102(e) as being anticipated by Seeman (USP 5,278,051).

Seeman discloses various structures that have been prepared from polynucleotides. Such structures include those in figures 2 and 7.

The term "VPM" is not defined with sufficient specificity to preclude polynucleotides. The term at issue encompasses any molecule with branch points, such that formation of covalent (or even non-covalent) conjugates is facilitated. Thus, there is nothing to preclude the possibility of both the VPM and the BAM being a polynucleotide. The structures in each of figures 2 and 7 can be viewed as conjugate between a "first" polynucleotide and a "second" polynucleotide; the structures can be viewed as as conjugate between a "first" polynucleotide and a "second" and "third" polynucleotide. Thus, for example, the structure in figure 2 can be viewed as comprising a VPM to which the following polynucleotide is conjugated: CAGGTGCTG

In the case of figure 7F, each of the depicted structures is branched. Accordingly, each of the structures in figure 7F comprises a VPM to which is covalently bonded a polynucleotide.

Thus, the claims are anticipated.

\*

Claims 22, 26, 27, 29, 30, 58-61 are rejected under 35 U.S.C. §102(e) as being



anticipated by Seeman (USP 5,386,020).

Seeman discloses (e.g., fig. 3) a method of forming a cubical structure using polynucleotides. The precursor of the cube is a branched polynucleotide. This branched polynucleotide qualifies as a "conjugate" between a VPM and a polynucleotide. There is nothing in the specification to exclude the possibility that a VPM can be a polynucleotide.

Thus, the claims are anticipated.

\*

Claims 22-24, 33-35, 54, 56, 59-63 are rejected under 35 U.S.C. §102(e) as being anticipated by Tomalia (USP 5,527,524) or Tomalia (USP 6,177,414).

Tomalia ('524) and Tomalia ('414) both disclose starburst conjugates which comprise biologically active compounds. The term "VPM" is not used, but clearly the compounds qualify, especially since the term "non-polymeric" does not appear in the claims.

Thus, the claims are anticipated.

\*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time

the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 22-25, 33, 35-37, 44 are rejected under 35 U.S.C. §103 as being unpatentable over Greenfield (U.S.P. 4,933,288) or Woo (U.S.P. 5,130,116) or Ferris (USP 4,808,705) or Sivam (USP 4,981,979).

As indicated previously, each of Greenfield, Woo, Ferris and Sivam teaches immunoconjugates. Formula 2 (page 4, specification) which is encompassed by claim 22, encompasses immunoconjugates. Claim 22 requires "branching groups", but this requirement is met by the lysines and cysteines of the immunoglobulin which react with the therapeutic agent.

In response to the foregoing, applicants have argued that applying the term "predetermined" to a structure of an organic compound somehow limits or changes its structure. However, this is not the case. First, consider the meaning of the term "predetermined" as applied to chemistry in a broad sense. Consider, for example, the simple compound benzene. This compound was discovered in compressed oil gas in

the year 1825. At the time of its discovery, its structure was not "predetermined" by any chemist. Its structure was, however, "predetermined" by the presence of carbon and hydrogen, by the temperature and pressure that gave rise to it, and by the laws of chemistry and physics. So in one sense, the structure of benzene was "predetermined" long before its discovery. Moving on to the present day, any time that a chemist synthesizes a compound, or even draws the structure of it on paper, the structure of that compound is "predetermined".

Moving on next to claim 22, this claim recites the following:

"the number of branching groups predetermines the valency of said platform molecule and [the] location of attachment sites"

However, this statement (at least with regard to the matter of the valency) is true for any and all organic compounds, regardless of whether they have 1000 branching groups, 10 branching groups, or even **no** branching groups. Consider first the case where there are no branching groups. According to one interpretation, a simple compound like n-hexane would qualify. This compound has no branching groups, a valency of zero, and no attachment sites. Yet it is still true that the number of branching groups determines the valency of this molecule. The number of branching groups is zero, and (at least partly) **as a consequence** of this, the valency is also zero. Or consider the compound adipic acid. If this compound is reacted with a biologically active peptide (in the presence of a carboxyl activating agent), the result is a compound with a

valency of two, but no branches (other than what may be present on the peptide itself).

But it still remains the case that the number of branches has "predetermined" the valency. These two results (with n-hexane and adipic acid) can be reconciled by observing that the number of branching groups imposes an *upper limit* on the valency. Whether this upper limit is ever achieved, however, it remains the case that the number of branches is partly responsible for "predetermining" the valency. Consider next the simple compound lysine methyl ester. This compound has one branching group, a valency of two, and two attachment sites. The fact that there is just one branching group **predetermines** the valency of two, and the presence of two attachment sites. Thus, no matter what the structure of a compound is, and how many branch points there are, the valency of the compound is determined (at least in part) by the number of branch points.

Next, applicants have pointed to conjugate 20-II in figure 6B. Applicants have characterized this structure as having two branches and a valency of four. It is also indicated that prior to conjugation of the oligonucleotide, there were four "attachment sites". While these assertions may be correct, there is more to the analysis. Suppose that instead of four oligonucleotides being attached, there were only three. One could then argue that the resulting molecule has a valency of three. The critical question then would be, is this valency of three "predetermined" by the presence of two branches, or is the valency of three not "predetermined" by the presence of two branches? The

examiner would argue that state of "predetermination" has not been lost merely because one potential attachment site is unoccupied. A closely related issue is what exactly is meant by an "attachment site"...? The compound in figure 6B contains the following grouping of atoms, wherein "R" is hydrogen:



Suppose instead that variable "R" were hydroxyl, or carboxyl, or a carboxyaldehyde or an epoxide group. For any one of these cases, how many "attachment sites" would there be? It appears that there is no rigorous definition of the term "attachment site" in the specification. One might infer, however, that applicants regard the term "attachment site" as meaning a functional group (on the VPM) which will react readily with a functional group on the BAM. This leaves considerable uncertainty as to what is meant by "readily". Consider again the structure in figure 6B, and again suppose that one of the four groups designated as "PN" were absent and that a "free" phosphate (monoester) group were present. According to the information in the specification, it would appear that this phosphate monoester would not qualify as an attachment site. There appears to be no discussion in the specification (e.g., pages 94-98) about how to attach the group designated "PN" to the phosphate monoester. This is not to say that such an attachment is chemically impossible, only that the specification is ambiguous as

to whether a phosphate monoester (i.e., the compound of fig 6B minus the group "PN") would qualify as an attachment site or not. And as indicated above, if there were another functional group present (e.g., an alcohol or carboxylic acid), this would add further uncertainty to the number of "attachment sites". Thus, to reiterate the point made above, if one of the "PN" groups were removed from the structure of figure 6B, the number of branches would remain at two, the number of BAM's would be three, and the number of "attachment sites" would be either one or zero, depending on one's point of view. The important point, however, is that the valency is still "predetermined" by the number of branches in the molecule. By way of contrast, suppose that claim 22 had instead stated that the valency must be exactly equal to two times the number of branches. If this is what the claim had stated, this limitation would be effective to overcome the teachings of the references. But the claim imposes no such limitation. In reality, the number of branches and attachment sites determines only an upper limit on the valency, and not necessarily the observed valency.

The rejection is maintained.

\*

Claims 22-25, 33, 35, 37, 62 are rejected under 35 U.S.C. §103 as being unpatentable over Denkwalter (USP 4,289,872) in view of Gerzon (USP 4,415,590).

Denkwalter discloses branched polylysine. Denkwalter does not explicitly state

that a "multiplicity of biologically active molecules" should be bonded to the polylysine. Gerzon discloses that the amino acid lysine is a biologically active molecule, and more specifically a biologically active molecule that inhibits replication of herpesvirus. Gerzon does not disclose valency platform molecules.

The branched polylysine disclosed by Denkwalter is no less a "valency platform molecule" than are the compounds disclosed in the instant application. In addition, the valency of the molecule is determined by the number of branching groups (lysine, in this case); the more lysines, the greater the valency. According to one interpretation, the external lysines would constitute the BAM's, and at the same time, the lysines to which the external lysines are "conjugated" would provide the "attachment sites". However, there are other interpretations, in part because of the term "comprises" in claim 22. Thus, one could mentally "strip out" the external lysines and proceed to the next "layer" of lysines; these lysines could then be viewed as the BAM's, and the lysines to which these lysines are "conjugated" would provide the "attachment sites". Thus, by any interpretation, the polylysine contains branching groups, BAM's, and "attachment sites".

Even if claim 22 were amended to recite that 100% of all attachment sites must bear a BAM, the claims would still be rendered obvious.

\*

Claims 22-24, 26, 29, 30, 58-60 are rejected under 35 U.S.C. §103 as being unpatentable over Levy (USP 4,349,538).

Levy discloses compositions that comprise polynucleotides and polylysine. The bonding between the polynucleotides and polylysine is ionic, rather than covalent. Levy does not describe the polylysine as a branched molecule.

There are two issues here. First, what exactly is meant by the term "VPM", and more specifically, what are the criteria that must be met in order for a molecule to be considered "branched"...? The second issue is that the claims recite the term "conjugate" without specifically mandating covalent bonding. Thus, "ionic bonding" would be included.

With regard to the question of branching, a simple molecule such as 3-methylhexane could be viewed as such. A simple molecule such as isoleucine could be viewed as having two branch points. In Levy ('538), the lysine was presumably "linear" rather than "branched" (as in Denkwalter USP 4,289,872). However, there is more to the analysis. A peptide chemist might argue that, in considering the polylysine of Levy as consisting of units of amino acids, those amino acids are bonded together in a "head to tail" fashion, and thus, if the overall molecule is viewed as consisting of amino acid units only, one could say that it is linear. But if one looks at the arrangement of atoms, it is clear that each lysine unit is itself branched. Accordingly, the number of branch points



is equal to the number of the lysines present. Consider, moreover, the the description of the term "VPM" on pages 3-5 of the specification. It is stated that any compound that conforms with formula 1 (page 4, spec) would qualify as a VPM.

Consider what formula I encompasses.



As stated (page 4, line 25+) variable  $G^{[1]}$  can be any linear or branched chain that contains carbon and nitrogen atoms. A peptide, of course, comprises the following:



For the case where each amino acid contains at least one carbon atom, the structure may be represented as follows:



If, for example, each of the "R" groups were to represent a butylene group (which is present in the side chain of lysine), the result would be a branched molecule, in which the sum of the carbonyl groups is equal to the number of branch points. Consider next substituent variable  $T^{[1]}$  of formula 1. As indicated on pages 5-6 of the specification, substituent variable  $T^{[1]}$  can be just amino. Thus, polylysine conforms with the structure of formula 1. [It is noted that the term "non-polymeric" is used on page 3, line 22 of the specification; however, this limitation does not appear in the claims].

The next point to be made (as indicated above) is that the instant claims do not actually require covalent bonding between the BAM and the VPM. The term "conjugate" would encompass ionically bonded compounds. In the case of polylysine/ polynucleotide conjugates, the ionic bond occurs between the (cationic) lysine *epsilon* amino groups and the (anionic) phosphate groups of the polynucleotide.

\*

Claims 22-24, 26, 29, 30, 58-60, 63 are rejected under 35 U.S.C. §103 as being unpatentable over Borel (*Annals of the New York Academy of Sciences* **475**, 296-306, 1986) or Borel (*Journal of Immunological Methods* **67** (2) 289-302, 1984).

Borel (1984) and Borel (1986) both disclose conjugates of oligonucleotides with KLH and with antibodies. The oligonucleotides are bonded via a linker to the lysine *epsilon* amino groups. Lysine is a "branching group". The immunoglobulin or the KLH is a "VPM". The number of branching groups "predetermines" the valency of the VPM, or at least, the number of branching groups "predetermines" the maximum valency that is attainable. It may be the case that fully 100% of the lysines do not react with the aldehyde group. However, one can argue that this outcome is "predetermined" by the practitioner, who has selected the reaction conditions. Further, the claims do not require that the valency be equal to two times the number of branching groups; the claims do not require that the valency be equal to the number of branching groups. The

claims impose no numerical value whatsoever on the relationship between the number of branching groups and the valency.

Thus, the claims are rendered obvious.

\*

Claims 22-24, 26, 29, 30, 58-60, 63 are rejected under 35 U.S.C. §103 as being unpatentable over Leonetti (*Gene* 72, 323-332, 1989).

Leonetti discloses conjugates of oligonucleotides and polylysine, wherein the oligonucleotides are covalently bonded to the *epsilon*-amino group of each lysine. Polylysine, as it happens, is a "VPM". Polylysine contains branching group in an amount equal to the number of lysines present. The number of lysines "predetermines" an upper limit to the number of oligonucleotides which will become covalently bonded.

Thus, the claims are rendered obvious.

\*

References 9 - 15 were stricken from the IDS because of the absence of a translation.


It is suggested that an abstract of each be provided, and the following (for example) be listed in the "other documents" section:      **Abstract of JP 62-503171**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
**DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800**